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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/774,397 | 01/31/2001 | Theresa A. Hadlock | 00786-446001 | 3080 |

26161 7590 01/20/2004

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| EXAMINER |
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JACKSON, GARY

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| ART UNIT | PAPER NUMBER |
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3731

DATE MAILED: 01/20/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/774,397

Applicant(s)

HADLOCK ET AL.

Examiner

Gary Jackson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-43, 45-49 and 55-59 is/are rejected.
- 7) ☒ Claim(s) 5, 44 and 50-54 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

This action is a response to applicants' Request for Continued Prosecution filed December 12, 2003.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 4, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stensaas et al. The patent to Stensaas et al discloses a nerve-regenerating conduit being in the form of a roll having a spiral of about one full rotation to support the nerve endings. The applicants' specification is silent as to the criticality or benefits of having at least 3 ½ rotations of the conduit. Stensaas et al teach the concept of forming a spiraled conduit to secure the nerve ending without using sutures and other advantages.

It would have been obvious to one having ordinary skill in the art to form Stensaas et al device of at least 3 ½ full rotations so as to tightly secure nerve endings in an end-to-end fashion. It is inherent that more than one full rotation will securely hold the nerve ends in the desired fashion.

Claims 2-3, 8-18, 40-43, 45-46 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Butler et al in view of Stensaas et al, Goosen et al (US Patent 4,806,355) and Hadlock et al publication "A Polymer Foam Conduit Seed with Schwann Cells Promotes Guided Peripheral Nerve Regeneration". Again, Butler discloses a method for regenerating nerves with use of a cell-encapsulating device. Stensaas et al teaches the use of a rolled device for regenerating nerves. Hadlock et al discloses

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providing cells suspended in nerve regeneration conduit. Goosen suggest encapsulating cells.

It would have been within the purview of one having ordinary skill in the to provide Butler with the spiral roll device of Stensaas et al so as to wrap the nerve ends for tighter grip rather than inserting the ends into a grip. See figure 7A of Stensaas et al. In the alternative, it would have been obvious to one having ordinary skill in the art to provide Stensaas et al with an encapsulated layer of cells to promote nerve regeneration.

Claims 19-39, 47-49 and 55-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stensaas in view of Butler, Goosen and Hadlock in further in view of Dionne et al (US Patent 5,773,286). The latter reference suggests encapsulating neurotrophic agents in separate spheres. It would have been obvious to one having ordinary skill in the art to provide Stensaas et al in combination with Butler, Goosen and Hadlock with encapsulated neurotrophic agents to promote nerve growth.

Allowable Subject Matter

Claims 5, 44 and 50-54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed December 12, 2003 have been fully considered but they are not persuasive. The examiner previously disagreed with applicants' argument that Stensaas does not disclose a method that includes a rolling a support around nerve ends since figure 7 and column 16, line 54 to column 18 disclosed such. The examiner's position on the claims as amended is that once it is suggested in the art to form a nerve

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guidance conduit having spiraled cross-section that facilitate securing the nerve endings; it would have obvious to form a conduit having any number of spiraled rotations including at least 3 ½ full rotations.

Even further, Stensaas et al suggest repairing injured nerves and since a crushed nerve is considered an injured nerve, it would have obvious to repair a crush nerve with Stensaas's device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary Jackson whose telephone number is (703) 308-4302. The examiner can normally be reached on Mon.-Thurs. 7:30 am to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 308-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Gary Jackson
Primary Examiner
Art Unit 3731

GJ
December 29, 2003